Remarks

Claims 1-11, 19, 25, 31, and 44 are pending, of which claims 1-11, 19, and 31 are currently under examination. By this amendment claims 1, 8-11, 19, and 31 are amended; no claims are canceled; and no new claims are added. No new matter is introduced.

Each of claims 1, 11, 19, and 31 is currently amended to specify that the compositions used in the claimed methods are isolated HSP60, isolated HSP65, or therapeutically effective fragments thereof. Basis for these amendments can be found throughout the specification.

Each of claims 8-10 is amended to substitute the term heat shock protein with the term agent in order to make more clear the antecedent basis for the claims.

None of the foregoing amendments is made in order to overcome prior art.

Applicants acknowledge that the Examiner indicated that all the references listed in the IDS filed 11 June 2001 have been considered.

Applicants also acknowledge that the Examiner has withdrawn the previous specification objections.

Applicants further acknowledge that the Examiner has affirmatively withdrawn the previous rejection of claims 1, 3-7, 11, 19, and 31 under 35 U.S.C. 103(a).

Claim Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner indicated that claims 1-11, 19, and 31 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. More specifically, the Examiner asserts that claim 1 is unclear in "HSP60/65". It appears the Examiner understands the use of the term "HSP60/65" to refer to a fusion between HSP60 and HSP65. In addition, the Examiner asserts that claims 1-11, 19, and 31 are rejected for recitation of "peptide analog of isolated HSP60/65"

because, according to the Examiner, the specification does not define what the peptide analog of isolated HSP60/65 heat shock protein is, and the recitation is unclear as to whether or not the said analog encompasses any fusion of the said protein, or protein mimetic thereof.

In response, it is to be noticed that claims 1, 11, 19, and 31 have been amended to make clear that the claims are directed to methods involving the use of isolated HSP60 heat shock protein, isolated HSP65 heat shock protein, and therapeutically effective fragments thereof. The terms "HSP60/65" and "peptide analog of isolated HSP60/65" no longer appear in the claims. Therefore the bases for the rejections have been removed. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-11, 19, and 31 under 35 U.S.C. § 112, second paragraph.

For the record, Applicants maintain their position, at least for grounds set forth in the response to the previous Office Action, that the term "peptide analog", although no longer present in the claims as currently amended, is not indefinite.

Claim Rejections Under 35 U.S.C. § 112, first paragraph

The Examiner indicated that claims 1-7, 11, 19, and 31 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description. More particularly, the Examiner asserts that amended claims 1, 11, 19, and 31 recite "peptide analog of an isolated HSP60/65" without clear support for this term. Further, the Examiner asserts that claims 1-7, 11, 19, and 31 are rejected because the specification does not describe a method of treating or suppressing a vascular disorder state comprising administering to a subject a composition comprising a peptide analog of the HSP60 or/and HSP65. The Examiner further asserts that the specification only teaches the method for treating or suppressing a vascular disorder state comprising administering to a subject a composition comprising an isolated HSP60 or HSP65 protein. For reasons set forth below, Applicants respectfully disagree and request the Examiner to reconsider and withdraw the rejection of claims 1-7, 11, 19, and 31 under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description.

In response, it is first to be noticed that the claims are currently amended to remove the term "peptide analog of an isolated HSP60/65". Applicants therefore respectfully submit that the basis for the rejection of claims 1, 11, 19, and 31 for recitation of the term recite "peptide analog of an isolated HSP60/65" is overcome.

Second, Applicants wish to call to the attention of the Examiner the passage at page 11, line 35, to page 12, line 6, which describes peptide fragments of HSP65. In particular, the cited passage describes peptide fragments of HSP65 at least 10 amino acids long that occur between amino acid residues 201-300. The fragments are disclosed there to include, for example, fragments having amino acid residues 201-210, 211-220, 221-230, etc., as well as amino acid residues 202-211, 212-221, 222-231, etc., as well as amino acid residues 203-212, 213-222, 223-232, etc., and so on, i.e., every 10-mer containing at least one amino acid between 201-300. Applicants submit that this description adequately describes what is meant by fragments of HSP65, particularly when coupled with the passage at page 22, lines 10-28 of the specification, which describes what is meant by "therapeutically effective fragment". Thus Applicants respectfully submit that, contrary to the Examiner's assertion, the specification teaches not only the method for treating or suppressing a vascular disorder state comprising administering to a subject a composition comprising an isolated HSP60 or HSP65 protein, but also the method for treating or suppressing a vascular disorder state comprising administering to a subject a composition comprising a therapeutically effective fragment of an isolated HSP60 or HSP65 protein. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-7, 11, 19, and 31 under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description.

The Examiner further indicated that claims 1-7, 11, 19, and 31 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. More particularly, the Examiner noted at page 8 of the Office Action that the specification provided insufficient guidance and no working examples as to the fragment of an isolated HSP60/65, and further, at page 10 of the Office Action, that the generic phrase "peptide analog" reads on functional analog of HSP65 or HSP60, which encompasses any non-HSP protein or any biomolecule as long as it has ability of mimicking inflammatory response-suppressive activity of heat shock protein. For reasons set

forth below, Applicants respectfully disagree and request reconsideration and withdrawal of the rejection of claims 1-7, 11, 19, and 31 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

In response, it is to be noticed the Examiner already acknowledged, on page 4 of the previous Office Communication, that the specification is enabling for a process of treating a vascular disorder in a mammal comprising administering to a mucosal surface a composition comprising HSP60 or HSP65 or a fragment of HSP65. Further, as pointed out above, the claims as currently amended are directed to methods involving the use of isolated HSP60 heat shock protein, isolated HSP65 heat shock protein, and therapeutically effective fragments thereof. The term "HSP60/65" no longer appears in any claim. Such limitations make clear that the claims are not so broad as to encompasses any non-HSP protein or any biomolecule as long as it has ability of mimicking inflammatory response-suppressive activity of heat shock protein. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-7, 11, 19, and 31 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

Summary

Applicants believe the claims under examination are in condition for allowance. Should the Examiner agree, Applicants are prepared to cancel pending claims that are withdrawn. An early and favorable response is earnestly solicited.

Respectfully submitted,
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